#1382

PPIs

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

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Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1-23, 12420
Parklawn Drive
Rockville MD 20857

Public Citizen's Health Research Group Comments
on
Prescription Drug Product Labeling; Medication Guide Requirements

Public Citizen representing 90,000 consumers, urges the FDA to enact long over due regulations requiring the distribution of agency approved written information to prescription drug consumers. Revoking the simple, sensible mandatory patient package insert (PPI) program in 1982 has left millions of prescription drug consumers dangerously ignorant about their medications. The FDA's medication guide proposal only perpetuates the misguided hope that there can be a voluntary private sector solution to the public's drug information needs and will only deny access to vital information that the public needs to protect themselves from drug induced injury or death for at least four more years.

"Inadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury and related costs to the health care system." [1]

"The Food and Drug Administration (FDA) estimates that the annual cost of hospitalizations due to inappropriate prescription drug use is $20 billion."[2]

Ralph Nader, Founder

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The above statements summarize the consequences of a federal agency responsible for the public's health yielding in 1982 to the pressure of a pharmaceutical industry that claims to operate for the public's good and to national organizations representing doctors and pharmacists who are sworn to help and protect the public before all else.

The value of consumer drug information has been debated and studied to "death." The evidence is in, and it is clear; consumers benefit when given access to well-written drug information, and consumers can comprehend the information. Assertions from drug company and professional trade groups opposing the distribution of consumer drug information have been paternalistic, fallacious and self-serving.[3] Consumers and consumer groups support the distribution of comprehensive written drug information as does the FDA. Yet, American prescription drug consumers are still denied access to information that can be used prevent possible drug induced injury or death.

A well-documented review of the history, research and issues surrounding consumer drug information was presented by the FDA in the proposed rule announcing the Medication Guide requirements.[1] Only if history and evidence are ignored can any but the following conclusions be reached:

I. Inadequate access to appropriate drug information is a major cause of inappropriate use of prescription drugs.

II. The inappropriate use of prescription drugs is a serious preventable public health problem.

III. Voluntary private sector solutions to provide adequate access to appropriate drug information have failed.

IV. To reach most of the public, distribution of consumer drug information must be mandatory.

V. To be accurate, consistent and noncommercial, the content of consumer drug information must reflect the current legal requirements for a drug's use.

UNKNOWN RISKS

Prescription drug consumers have the same right to information as those persons undergoing the simplest of surgical procedures. The disclosure of risks and benefits before surgery is an accepted part of our health care system guided by the principle of informed consent. This principle recognizes the individual's right to

information that is essential in making a personal judgement about accepting or rejecting the possibility of injury from a surgical procedure. Consumers of prescription drugs and surgical procedures share a common prospect; both assume individual risks of possible irreparable injury or death from their respective therapeutic interventions. In contrast to those undergoing surgical procedures prescription drug consumers face unknown risks when prescribed powerful therapeutic agents, perhaps for a lifetime, with no more information than the name of the drug, a sentence on the prescription label and "sticky-reminders" on the bottle.

THE MYTH OF A PRIVATE SECTOR SOLUTION

In 1979, after spending years studying the information needs of prescription drug consumers, the FDA proposed a simple and sensible plan that would have given the public accurate, thorough and understandable written information about prescription drugs. The plan required mandatory distribution of FDA approved drug information with each new and refilled prescription through patient package inserts or PPIs. The FDA's own research showed broad public support for the plan and that opponents' arguments to PPIs were groundless. Tragically, in 1982 an agency whose primary responsibility is the public's health capitulated to political pressure from industry and professional trade groups and canceled a program designed to prevent serious drug induced injury to consumers.

During the 1982 hearings that disemboweled the PPI plan promises were made by representatives of the pharmaceutical industry and pharmacy and medicine trade groups that if the FDA withdrew their mandatory PPI plan the private sector would develop systems to meet the drug information needs of the public. This promise was never kept. It is time that the FDA acknowledges that private sector promises are made to protect private sector interests, not the public's health.

The FDA's new medication guide proposal would extend the private sector's opportunity to voluntarily exercise its initiative until the year 2000. This will only deny the public access to vital drug information for at least four more years. The outcome of allowing another four years of a voluntary private sector solution should be patently obvious to the FDA. In 1982, Public Citizen commenting on this issue made the following prediction that is as true today as it was when written:

> *"The flurry of voluntary activities that FDA hopes will replace PPI's will simply never materialize. As soon as FDA withdraws the PPI program, these proposals will fade out of sight, leaving patients as much in the dark about their medications as they were before FDA proposed the PPI program. Patient drug information will be no more than a sensible idea destroyed by industry pressure,*

honored only by the lip service of a toothless committee."[a]

In the decade between 1982 and 1992 the percentage of patients receiving written information has increased from 5 to 14 percent in physicians' offices and from 16 to 32 percent in pharmacies. However, only 25 percent received more than brief "sticker-labels" on their prescription containers at the pharmacy.[4]

This is an example of how the private sector has responded to the serious public health problem of preventable drug induced injury. Credit for this meager increase in written drug information may have to go to government regulation, including FDA pressure, and state Boards of Pharmacy, not to private sector initiative. The 1990 Omnibus Budget Reconciliation Act (OBRA 90) requires pharmacists to counsel Medicaid recipients about their medications. Since this law went into effect at least forty states have extended the OBRA 90 mandate to cover all prescription drug consumers, not only Medicaid recipients.[5] The distribution of written information is less time consuming than pharmacists counselling the public about their drugs.

THE ELDERLY - THE HUMAN COST OF IGNORANCE

Inappropriate use of prescription drugs is a problem that is particularly acute for the elderly. The older age groups use more prescription drugs than their younger counterparts and are more likely to be taking multiple medications, which increases the probability of adverse drug reactions. The United States General Accounting Office report on Prescription Drugs and the Elderly cites research that estimates the percentage of hospitalizations of elderly patients due to adverse drug reactions to be 17 percent, almost six times greater than the percentage of hospitalizations due to adverse drug reactions for the general population.[2]

A recent, carefully controlled study examined the details of prescriptions of people using three or more drugs to treat chronic illnesses being discharged from a community hospital. The major results of this study listed below are evidence of the preventable risks faced daily by older prescription drug consumers.[6]

- 88% had one or more prescribing problems with prescriptions they were given.

- 22% of these had at least one potentially serious, life-threatening problem that could have occurred from the prescriptions as written.

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[a]*Comments of Eve Bargmann, MD, Public Citizen Health Research Group on FDA's proposed revocation of the patient package insert program. April 20, 1982.*

- 59% of the patients had been given one or more prescriptions in which the drug was an inappropriate choice.

- 28% were given an overdose.

- 48% were given drugs with one or more harmful interactions.

- 20% were given drugs that unnecessarily duplicated the therapeutic effect of another drug they were taking.

Life and injury is the cost that elderly Americans are paying because neither they nor their care givers routinely have access to clear, accurate and complete information about prescription drugs. The evidence shows that the current "system" of safeguards are not protecting this vulnerable group from preventable adverse drug effects. Before continuing to oppose the mandatory distribution of consumer drug information professional trade lobbies must explain to the public this damning evidence and the performances of the professions they represent in protecting the public from preventable adverse drug reactions.

INADEQUATE AND INCONSISTENT INFORMATION

The FDA evaluated drug information produced by eight different private sector sources that provide information on electronic media designed for use by retail pharmacists as an aid to consumer counseling at the time of drug dispensing. Consistency with current approved product labeling for three drugs was used to measure the accuracy and completeness of the private sector information sources. Only four of the eight sources produced drug specific information for the three drugs chosen and the other four produced only general therapeutic class information. The information communicated to consumers was judged on whether the directions for use were clear and whether risk information conveyed the significance of the risk, how to recognize adverse effects, and the proper response that a consumer should take if an adverse effect were to occur. Substantial differences in the private sector sources were found and the lack of detail and background information explaining risks in information from some of the sources was described as a special concern by the FDA.[1]

Below are examples of serious and needless omissions found in some the commercially available drug information sources reviewed by the FDA:

> *"None of the eight sources mentioned the contraindications for the use of enalapril [Vasotec--a common drug used for heart problems and high blood pressure], i.e., allergic reactions or swelling (angioedema) on previous treatment with similar drugs. Two the sources failed to warn the patient about symptoms of angioedema, a potentially deadly allergic reaction. Of the six*

including such symptoms (i.e., swelling of face, extremities, eyes, lips, tongue or difficulty in swallowing or breathing), only one advised the patient experiencing such symptoms to take no more drug and to seek medical attention immediately."

Inconsistent and incomplete communication of potentially life saving drug information to consumers is unacceptable. For the public's safety consumers need a clear, accurate and complete reflection of a product's approved labeling and this must be the minimum standard by which consumer drug information is judged. Appropriate and safe use of prescription drugs also demands that important product labeling changes are accurately, completely and consistently communicated to the public. The private sector, with a myriad of competing vendors, cannot approach the simplicity and safety of a uniform mandatory system of distributing consumer drug information based on a drug's current legal labeling requirements.

THE CURIOUS CALL FOR MORE RESEARCH

The goal of improving drug compliance is to ensure that consumers understand the importance of taking their medications and taking them all correctly. Professional trade groups that have long opposed the mandatory distribution of consumer drug information are now making a curious call for basic research into finding ways to improve compliance before giving the public access to drug information.[7] Calling for more compliance studies is side stepping the important public health issue of preventable adverse drug effects that these groups have not addressed, and is only a way to continue to obstruct access to vital drug information.

It would be hard to imagine a successful intervention to improve compliance that would not include comprehensive drug information written for consumers. This fact makes the continued obstruction by some trade groups of consumer drug information pointless. Weighing the published evidence of harm from preventable adverse drug reactions against a purported need for compliance research and deciding that compliance must come first is simply indefensible.

THE EUROPEAN PARADOX

A baffling paradox is the comparison between the failed attempts in the US to provide consumers with written prescription drug information and the response within the European Community (EC) to this important public health issue. The EC adopted legislation in 1992 requiring that consumer drug information approved by a member country's drug regulatory authority be distributed with all prescriptions by December 1998. Beginning January 1, 1994 European consumers were mandated to receive written drug information leaflets with every prescription for newly marketed drugs.[8] The EC's rational for the regulation was simple:

". . . the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information."

Following the requirements mandated by the EC, in the United Kingdom (UK) all new drugs approved for sale after January 1, 1995 were distributed with consumer drug information leaflets. Drugs already on the market, both brand name and generic products, will be dispensed with written information for consumers by September 1998. For those persons confined to a hospital the drug information would be provided on request. At this time, information requirements for nursing home residents have not been decided.[9] A practical solution would be to provide the drug information to those helping with the medication management of a nursing home resident such as a spouse, family member or friend on request.

Regulation prevents consumer drug information from becoming another advertising platform for pharmaceutical manufacturers by requiring that the content of consumer drug information leaflets be consistent with the current legal requirements for the drug's use in the UK. To ensure that leaflets meet these legal requirements, and do not contain advertising, the wording must first be approved by the Medicines Control Agency (MCA), the British equivalent of the FDA, before distribution to the public.[8,9]

In Appendix I are examples of consumer drug information leaflets produced in the UK by multi-national pharmaceutical manufacturers that operate in both the UK and the US. The leaflets were field tested in groups of consumers for clarity by at least one manufacturer before being sent to the MCA for final approval. A senior marketing official for one of the world's largest pharmaceutical manufacturers described the process of writing these leaflets as relatively "painless" from the company perspective. The hard work has already been done. The information in the approved product labeling only needs to be put in language that can be used by consumers.[b] Judging by the British experience the "complexities" of mandatory consumer drug information are largely in the minds of their US opponents.

The European approach to consumer drug information is reminiscent of the FDA's 1979 PPI proposal; simple, comprehensive and mandatory. Our European cousins may have addressed the consumer's right to prescription drug information later than in the US, but European consumers are already receiving vital prescription drug information.

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[b]*Personal Communication, December 5, 1995 with Mr. Mark Archer, Senior Project Manager for Marketing, Merck Sharp & Dohme, United Kingdom.*

CONCLUSION

The distribution of clear, accurate and complete information based on a drug's approved labeling with all prescriptions is a simple and sensible idea that should have been finalized and put into practice in the US sixteen years ago. This 1979 idea is now becoming a reality in the EC. The FDA's proposal for medication guides will only further delay consumer access to vital drug information for at least four more years, but if history is the guide, it will be for much longer if the FDA does not find the determination to resist the pressure of drug company and professional trade groups. All that has ever stood between US consumers and access to potentially life saving drug information has been the FDA's resolve to resist these pressures.

REFERENCES

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8. Council Directive 92/27/EEC of 31 March 1992 on the labeling of medicinal products for human use and on package leaflets. Official Journal of the European Communities1992; 35:8-12.

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APPENDIX I

APPROVED PATIENT INFORMATION LEAFLET

LIPOSTAT TABLETS

Your doctor has prescribed Lipostat tablets for you. Please read this before you take your medicine.

This leaflet gives a summary of information about your medicine. If you want to know more, or are not sure about anything, ask you doctor or pharmacist.

REMEMBER
This medicine is for YOU. Only a doctor can prescribe it for you. **NEVER** give it to anyone else. It may harm them even if they have the same symptoms as you.

WHAT IS IN LIPOSTAT TABLETS?

The active ingredient in Lipostat is pravastatin sodium. Lipostat is one of a group of medicines called HMG-CoA reductase inhibitors which work by lowering your body's production of cholesterol.

The tablets are pink in colour and come in two different strengths: 10mg and 20mg . The tablets are available in blister packs of 28 tablets.

The other ingredients are croscarmellose sodium, erythrosine, lactose, magnesium stearate, microcrystalline cellulose and polyvidone.

Q. WHO SUPPLIES LIPOSTAT TABLETS?

PRODUCT LICENCE HOLDER:

E.R. Squibb & Sons Limited
Hounslow, Middlesex

PRODUCT AUTHORISATION HOLDER:

Bristol-Myers Squibb Pharmaceuticals Limited
Dublin, Ireland

MANUFACTURER:

Bristol-Myers Squibb Pharmaceuticals Limited
Moreton, Merseyside

Q. WHAT IS THIS MEDICINE FOR?

A. Lipostat is used to lower levels of cholesterol in the blood and should always be used together with a low fat diet. You probably feel quite well and would not notice you have high cholesterol, but too much of it in the blood stream is one of the important causes of heart attacks. Your doctor has prescribed Lipostat to try to reduce the chances of this happening.

BEFORE TAKING YOUR MEDICINE

Q. SHOULD I BE TAKING LIPOSTAT TABLETS?

A. DO NOT take these tablets if you answer YES to any of the following questions.

1) Are you pregnant or is there a possibility that you may become pregnant?

2) Are you breast feeding?

3) Have you had any problems with your liver that your doctor does not know about?

4) Have you had an allergic reaction to similar tablets or any of the ingredients in Lipostat Tablets?

5) Are you under 18 years of age?

Go back to your doctor as soon as possible to discuss your concerns and follow the advice given.

Q. CAN I TAKE ANY OTHER MEDICINES?

A. It is usually all right to take Lipostat with other sorts of medicines, however, if you are also taking a resin-type lipid-lowering agent such as cholestyramine or colestipol, Lipostat should usually be taken at least one hour before or four hours after you have taken the resin. Always tell your doctor about *all* other medicines you are using, even those you have bought from a pharmacy, supermarket or elsewhere.

Q. IS IT ALL RIGHT TO DRIVE?

A. Lipostat tablets do not usually affect your ability to drive.

Q. IS IT ALL RIGHT TO DRINK ALCOHOL?

A. Lipostat should not be taken by patients who regularly drink large amounts of alcohol. Alcohol intake should be kept within guidelines suggested by your doctor. It is particularly important to stick to these as alcohol can increase your cholesterol level. If you are not sure about this please talk to your doctor.

TAKING YOUR MEDICINE

Q. HOW SHOULD I TAKE LIPOSTAT TABLETS?

A. The usual dose of Lipostat is 10 – 40 mg once a day. Tablets should be swallowed with half a glass of water at bedtime.

Your doctor may do regular blood tests to ensure that your body is responding correctly to treatment.

Q. WHY IS LIPOSTAT TAKEN AT BEDTIME?

A. Your body produces the most cholesterol when you are asleep and Lipostat acts best when it is taken at night.

Q. SHOULD I TAKE THE TABLETS BEFORE OR AFTER MEALS?

A. It does not matter.

Q. HOW LONG SHOULD I TAKE THEM FOR?

A. It is important that you continue to take Lipostat until your doctor tells you otherwise. Your doctor will tell you to come back for regular check-ups. Keep your doctor's appointment even if you feel well.

Q. WHAT IF I MISS A DOSE?

A. If you miss a dose do not worry. Take your normal dose when it is next due. DO NOT take a double dose to make up for the one you missed.

Q. WHAT IF I TAKE TOO MANY TABLETS OR A CHILD SWALLOWS SOME?

A. Contact your nearest hospital Casualty Department or tell your doctor immediately.

UNDESIRABLE EFFECTS

Q. ARE THERE ANY UNWANTED EFFECTS OF LIPOSTAT?

A. Any medicine may cause some unwanted effects, but most people feel well while taking these tablets. A few people may develop rashes, headache, muscle pain, chest pain, tiredness or minor stomach upsets (diarrhoea or sickness) but these generally disappear after a week or so. Unwanted effects on the liver or kidney may occur but these are rare. If you experience any unpleasant or unusual effects whilst taking Lipostat, or if you want to discuss other problems before taking your medicine, arrange to see your doctor as soon as possible.

LOOKING AFTER YOUR MEDICINE

You will see an 'EXPIRY DATE' on the outer packaging of Lipostat Tablets. Do not use after this date.

Keep all your medicines where children cannot reach them, preferably in a locked cupboard or medicine cabinet. Keep Lipostat Tablets below 30°C. They should not get too hot or damp; so do not leave your tablets near a radiator, on a window sill or in the bathroom.

If your doctor tells you to stop taking these tablets, we suggest that you take any tablets you have left back to your pharmacist who will dispose of them safely.

Further information about cholesterol and self-help may be obtained from your doctor and from: Family Heart Association, Wesley House, 7 High Street, Kidlington, Oxford OX5 2DH.

DATE OF LAST REVISION: August 1995

Product	ZOCOR	Code	78744
Item	Patient Information Leaflet (UK)		
Based on	Data Sheet (and IPC No 0794)		
Typist	Barbara Rush (ZCR-002)	Date typed	07.08.95
Writer	Lesley Deane	Reader	
Technical Approval		Date	
Legal Approval Date			

78744

PLEASE READ BOTH SIDES OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR TABLETS

Keep this leaflet. You may want to read it again.

ZOCOR®

(simvastatin, MSD)

WHAT IS IN YOUR TABLETS?

Active ingredient

The active ingredient in 'Zocor' Tablets is simvastatin. 'Zocor' Tablets are available in three strengths. The peach-coloured tablets contain 10 mg simvastatin, the tan-coloured tablets contain 20 mg simvastatin and the brick-red-coloured tablets contain 40 mg simvastatin.

Other ingredients

Ascorbic acid EP, butylated hydroxyanisole BP, citric acid monohydrate EP, hydroxypropylcellulose EP, lactose EP, magnesium stearate EP, microcrystalline cellulose EP, pregelatinised maize starch BP, talc EP, red iron oxide E172, titanium oxide EP, yellow iron oxide E172, methylhydroxypropylcellulose EP.

HOW DO YOUR TABLETS WORK?

The active ingredient in your tablets is simvastatin. This belongs to a group of medicines known as 'HMG-CoA reductase inhibitors'. These work by reducing the amount of cholesterol your body makes. Cholesterol is vital to the normal functioning of the body, but if levels of cholesterol in the bloodstream are too high it can be deposited on the walls of the arteries. There it builds up to form plaques which can eventually block the blood vessel, just like scale furring-up a water pipe.

We only get a small amount of cholesterol from our diet; egg yolks and liver contain large amounts of cholesterol, but many foods like fruit, vegetables, and fish are quite low in cholesterol. Nearly all of the cholesterol in our bodies is made by our own livers.

WHO MAKES YOUR TABLETS?

Your tablets are made by Merck Manufacturing Division, Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland, for Merck Sharp & Dohme Limited, Hoddesdon, Hertfordshire, UK, who holds the Product Licence in the UK.

WHY DO YOU NEED TO TAKE THESE TABLETS?

Your doctor has done some blood tests which show that, even though you may be taking a low-fat diet, you still have too much of one type of fat - called cholesterol - in your blood.

You have been prescribed `Zocor' for the following reason, which your doctor will explain to you:

- You have high cholesterol in your blood; 'Zocor' should lower this level. It is generally accepted that a high cholesterol level in your blood adds to the risk of heart disease. The higher the level, the greater the risk. The presence of other factors, such as existing heart disease, high blood pressure, high blood sugar (diabetes), increased weight, lack of exercise, and smoking, adds greatly to the risk of development or progression of heart disease with high cholesterol.

Your doctor may also have prescribed 'Zocor' because:

- You have coronary heart disease (CHD). Cholesterol can cause CHD by clogging the blood vessels which carry oxygen and nutrients to the heart. This clogging, or hardening of the arteries, is called atherosclerosis. Atherosclerosis can lead to chest pain (called angina) and heart attack. If you have CHD, your doctor has prescribed 'Zocor' to help prolong your life, to lessen the risk of a heart attack, and to decrease the risk of needing a surgical procedure to increase the blood flow to your heart. 'Zocor' also slows the progression of atherosclerosis and may reduce the development of new atherosclerosis.

Your doctor will have explained the importance of staying on a low-fat diet as well as taking the tablets.

ARE THERE PATIENTS WHO SHOULD NOT TAKE THESE TABLETS?

Yes; do not take the tablets if:

1. You are or think you may be pregnant.
2. You are planning to become pregnant.
3. You are breast-feeding.
4. You are a woman who could bear children unless you are taking a reliable form of contraceptive other than the pill. If you are planning to become pregnant you must stop taking 'Zocor' at least one month before trying to get pregnant.
5. You have liver problems.
6. You have a rare inherited disease called porphyria.
7. You have had a bad reaction to this or similar medicines or to any of the ingredients in the past.

If you think any of these apply to you, do not take the tablets, go and talk to your doctor first and follow the advice given.

WHAT ELSE SHOULD YOU KNOW ABOUT TAKING YOUR TABLETS?

You should check with your doctor before taking 'Zocor' if:

- You have persistent muscle aches or pains.
- You are taking medicines called immunosuppressants, e.g. cyclosporin.
- You are taking other cholesterol-lowering medicines such as fibric acid derivatives (such as bezafibrate, fenofibrate, gemfibrozil).
- You are taking an antifungal drug called itraconazole.
- You are taking large doses (higher than 1 g a day) of niacin or nicotinic acid.

'Zocor' contains lactose as an inactive ingredient and may produce symptoms in lactose-intolerant individuals.

Your doctor may want to do simple blood tests to check your liver is working properly before and during your treatment with 'Zocor'.

WHAT ABOUT ALCOHOL?

Your doctor will have told you that you should always keep your alcohol intake to a minimum. If you are concerned about how much alcohol you can drink while you are taking 'Zocor', discuss this with your doctor.

CAN YOU TAKE 'ZOCOR' WITH OTHER MEDICINES?

'Zocor' may occasionally interfere with other medicines, so it is important that you tell your doctor about all the medicines you are taking, including those obtained without a doctor's prescription.

These are:

- Medicines for a heart condition, such as digoxin.
- Medicines for thinning the blood, e.g. warfarin.
- Two other kinds of lipid-lowering agents: fibric acid derivatives (e.g. bezafibrate, fenofibrate, gemfibrozil), and large doses of niacin or nicotinic acid.
- Immunosuppressant medicines, e.g. cyclosporin.
- An antifungal medicine called itraconazole.

If you are taking any of these medicines you should talk to your doctor before taking 'Zocor'.

HOW SHOULD YOU TAKE 'ZOCOR'?

You should take your tablets exactly as advised by your doctor or pharmacist. The usual starting dose is 10 mg per day for high cholesterol levels and 20 mg per day for coronary heart disease, given as a single dose in the evening. Your doctor may adjust your dose to a maximum of 40 mg per day, given as a single dose in the evening. Your doctor may prescribe lower doses, particularly if you are taking cyclosporin or have certain kidney conditions. Your doctor may need to change this dose in order to have the best effect. Do not take more or less than your doctor has prescribed.

Keep taking your tablets for as long as your doctor has asked you to.

WHAT IF YOU FORGET TO TAKE A TABLET OR TAKE TOO MANY?

If you miss a dose, just carry on with the next one as normal. Do not take an extra one to make up.

If you take too many tablets by mistake, contact your doctor AS SOON AS POSSIBLE.

WHAT UNWANTED EFFECTS COULD YOUR TABLETS HAVE?

Like all medicines, 'Zocor' may occasionally cause side effects in some patients. The most common side effects are stomach upsets (such as sickness, stomach pain, constipation, diarrhoea, and flatulence), rash, itchiness, weakness, or headache, indigestion. The following have also occurred: dizziness, hair loss, abdominal pain, abnormal sensations in the arms and legs.

Rarely, a few patients have experienced the following: liver disease, muscle disease presenting as pains and aches, or an allergic reaction to 'Zocor'. The allergic reaction may include some of the following: swelling of the face or neck, muscle and joint pains, joint and blood vessel inflammation, urticaria, a high temperature, flushing, difficulty in breathing, or tiredness.

If any of these happen, or you have any other unusual symptoms or feelings, stop taking the tablets and contact your doctor immediately.

HOW SHOULD YOUR TABLETS BE KEPT?

Keep your tablets out of the reach of children. Protect them from light.

Store in a dry place below 25°C.

Do not put them into another container as they might get mixed up.

If you have any tablets left over when your doctor tells you to stop taking them, return them to your doctor or pharmacist.

Do not take them past the expiry date which is clearly marked on the pack.

REMEMBER this medicine is for you. Do not share it with anyone else. It may not suit them.

HOW CAN YOU OBTAIN MORE INFORMATION ABOUT 'ZOCOR'?

This leaflet only gives you some of the most important patient information about 'Zocor'. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.

Product licence holder:

Merck Sharp & Dohme Limited

Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU

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NJ, USA

Date of issue: August 1995

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